



MAXRAY
MOBILE X-RAY SYSTEMS



COCOON TRAINING MANUAL

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Introduction

There are many beneficial uses of ionizing radiation; however, of equal importance we note that there are potential risks associated with its use. Radiation safety training is an important part of any radiation safety program. Receiving appropriate training ensures users are following proper safety practices to maximize the benefits of ionizing radiation while minimizing potential risks and maintaining a safe work environment.

In this training manual, we discuss basic X-ray safety in addition to specific safety information about operating the MaxRay Cocoon. The Cocoon is a small, lightweight, handheld X-ray system meant for dental radiology that is certified by the FDA and is completely safe when used as intended. All operators must read, and become familiar with, the User's Manual associated with the Cocoon system.



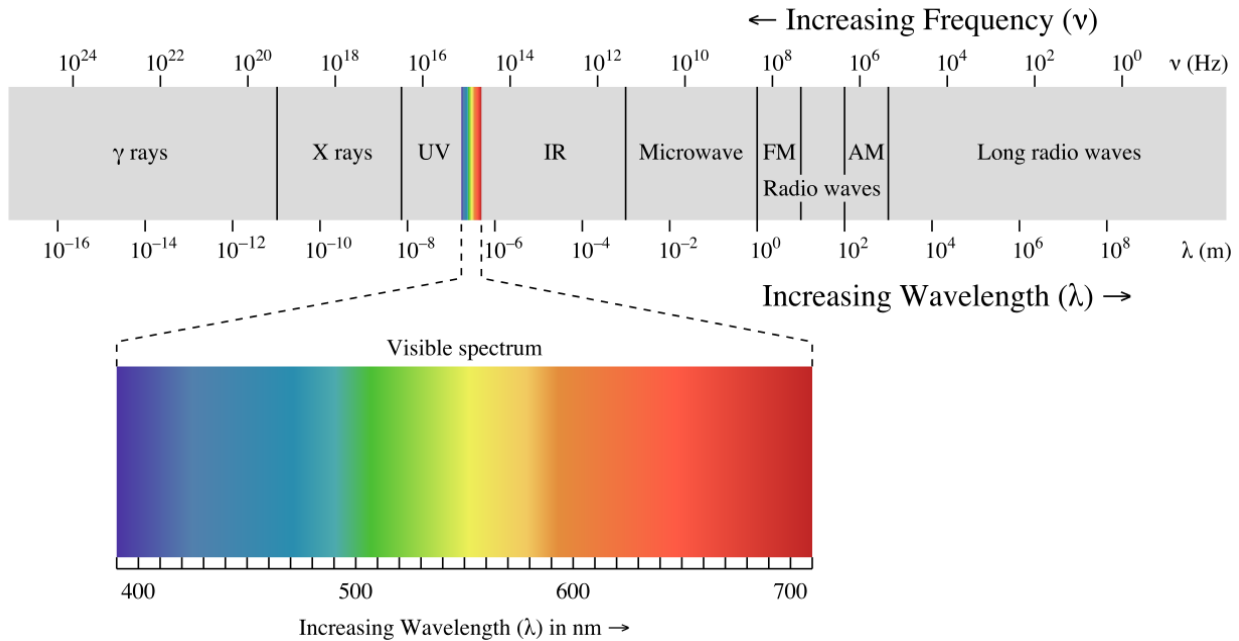
The MaxRay Cocoon mobile X-ray system.

This handheld unit is to be operated only by authorized personnel. DO NOT operate the Cocoon in any manner other than that specified herein, and in the User's Manual. And, DO NOT allow anyone other than trained and certified personnel to operate the Cocoon unit.

Background

What are X rays?

X rays are a form of ionizing radiation and are a part of the electromagnetic spectrum. X rays are the same as the light from the sun, except that their energy is much higher. As X rays travel through and interact with various materials, human tissue for instance, they transfer energy to the atoms of that material. This process of energy transfer can result in atomic ionization. X rays can penetrate certain materials, but they can be blocked or shielded with high-density materials.



The electromagnetic spectrum.

When living systems are exposed to ionizing radiation there is a risk for biological damage to occur. Exposure to X rays in the workplace, however, is highly regulated and current safety standards are very effective at keeping risks to a minimum.

How are X rays Generated?

X rays are produced in a type of vacuum tube specifically designed for that function. As power is applied to the tube, X rays are emitted in a prescribe fashion from a shielded housing.

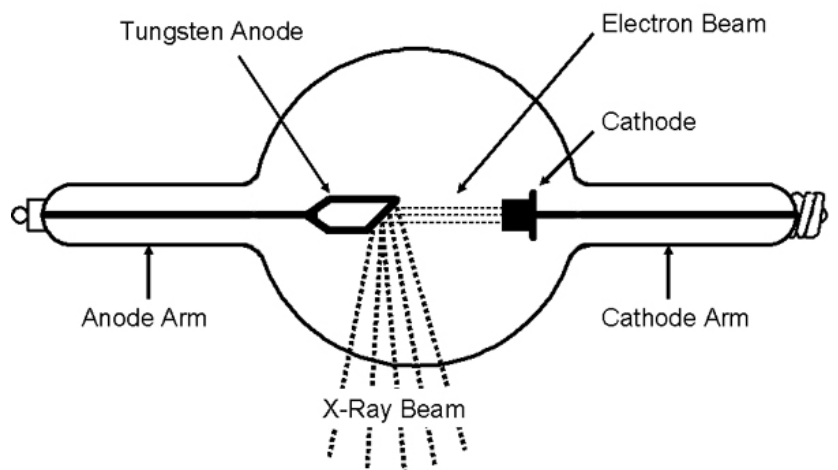


Diagram of an X-ray tube.

Generally, the three parameters that are usually adjusted by the X-ray technician (tube potential (kVp), tube current (mA), and time (sec)) establish the characteristics of the X-ray beam emanating from the tube. The tube potential determines the energy range of X rays and the tube current establishes the rate at which X rays are emitted. In the tube, X rays are produced by two means, Bremsstrahlung radiation and characteristic radiation. The two are described below.

Bremsstrahlung Radiation

This is the main type of radiation produced and occurs as the high energy electrons experience a sudden slowing down, or “breaking”, at the anode target. A spectrum of photon energies is produced. Bremsstrahlung is also known as “breaking radiation”.

Characteristic Radiation

This type of radiation is produced when an electron interacts with an inner shell electron of a target atom of the anode. As the inner shell electron is displaced, an electron from an outer shell drops to fill the vacancy. It is this process that releases characteristic X rays.

All X-ray tubes have some form of filtration, whether it be inherent to the design or added afterward to adjust the usefulness of the X-ray beam. The X-ray housing will have additional shielding to minimize “leakage radiation” that can cause unwanted exposure to the technician.

Primary and Scatter Radiation

Once X rays leave the tube housing, they are categorized as primary or secondary radiation. Secondary radiation is further characterized into scatter radiation and leakage radiation.

Primary radiation

This type of radiation describes the useful beam of radiation that is produced in the tube and exits the filtration window as designed. This is the radiation which is fundamental in producing the radiograph. Continued exposure to the primary beam can result in a significant hazard.

Scatter radiation

This refers to the radiation that is scattered after the primary beam interacts with the patient. The patient is therefore the major source of scatter radiation. Even though the primary beam is much more intense than scatter radiation, it is this scatter that is of primary concern when protecting the safety of the worker.

As stated above, **leakage radiation** refers to radiation from the X-ray tube that penetrates the device housing. Leakage is usually quite small relative to the primary beam and scatter.

Interactions with Matter

The interaction of X rays with matter is a random process. As tissue is exposed, the X rays may interact with the atoms of the material through which they pass. A small percentage of the X rays will pass through matter without interacting.

Those X rays that interact will do so by one of two methods, photoelectric absorption or Compton scatter.

Photoelectric absorption

In photoelectric absorption, the incident X-ray energy is completely absorbed in the interaction medium (e.g., tissue) and the X ray is removed from the beam and does not have the ability to scatter.

Compton scatter

With Compton scatter, the incident X ray scatters in the interaction medium and only a partial amount of original energy is absorbed. The remaining energy goes to the scattered X ray. This scattered energy is therefore available to be absorbed else where, for example, in the technician.

During the process of photoelectric absorption or Compton scatter, energy is transferred to the interaction medium. We quantify the effect of this energy absorption using a parameter called “absorbed dose”, i.e., the amount of energy absorbed for a given mass of absorbing medium. Someone’s risk from radiation exposure is directly proportional to the dose they receive. The regulatory agencies set limits on absorbed dose for workers and the general public to ensure that radiation risk is kept as low as practical.

Biological Effects of Radiation

While X rays are an important part of the diagnostic process, it is important to be aware that there is potential for biological damage to occur when exposed to ionizing radiation. Efforts should be made to evaluate the benefit and potential risk in order to avoid unnecessary radiation exposure. The benefits of medical/dental evaluation using X-ray technology are obvious, but the biological effects of ionizing radiation must be weighed against the benefits. These effects are commonly grouped into two categories:

Non-stochastic Effects (deterministic effects)

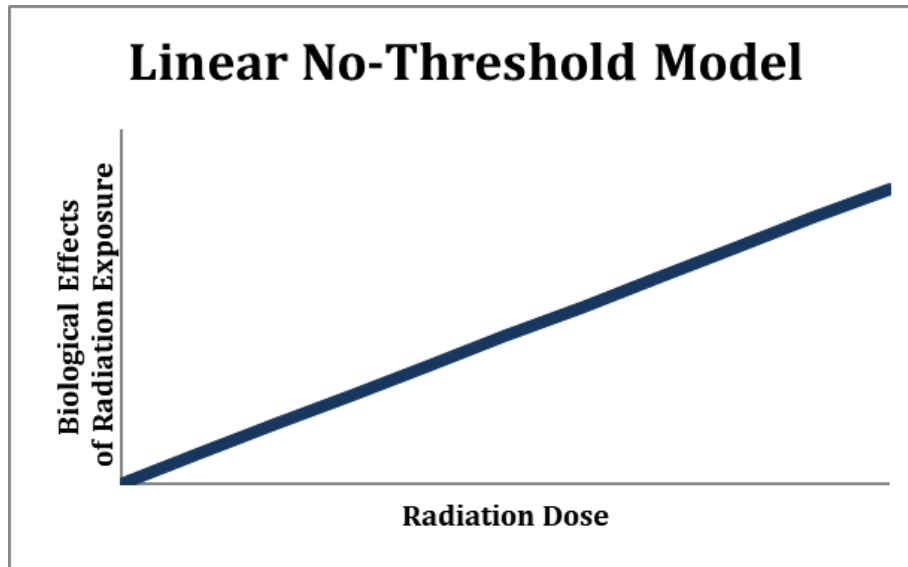
Non-stochastic effects related to those that are non-random and are directly related to the radiation dose received. For these effects to occur, a threshold dose must be met. Once the threshold has been exceeded, the severity of biological damage (e.g., skin burns, hair loss, reddening of the skin, cataracts) increases with the dose received. These effects are seen only after exposure to large doses of radiation (> 1,000 mSv), much larger than doses received when undergoing dental imaging.

Stochastic Effects (probabilistic effects)

Stochastic effects are randomly occurring and the severity of biological damage (e.g., cancer, birth defects) is independent of the dose received. Since it is based on probability, the chance of occurrence increases with radiation exposure. Stochastic effects are of typical concern when speaking of exposure to diagnostic X rays; radiation dose is very small; therefore, the only real potential outcome is the random chance of cancer.

Linear No-Threshold Risk Model

Because the random chance of cancer is so small, science must use a small set of existing data to predict cancer probability. Currently, the prediction is based on what's called a "linear, no-threshold model" and is intended to convey that cancer risk is thought to be proportional (linear) to dose, with zero dose resulting in zero risk (no-threshold). This model is conservative and follows the philosophy that it is better that risk be overestimated rather than underestimated.



Basic X-ray Safety

Safety Rules to Minimize Radiation Dose

ALARA. ALARA (As Low As Reasonably Achievable) is a safety principle that ensures radiation exposure levels are kept as low as practical, far below the exposure limits set by the regulatory agencies. It is a regulatory requirement and it is mandated that all radiation safety programs follow the ALARA principle.

In order to maintain ALARA, it is important to remember and practice the radiation protection triad of time, distance, and shielding:

- Time: minimize exposure time;
- Distance: maximize distance (between you and the source); and,
- Shielding: use appropriate radiation shielding.

The most effective shielding for X rays is lead. Patients should be shielded to protect their thyroid and reproductive organs, and the X-ray technician should wear a leaded apron. Some of the handheld X-ray systems come equipped with a leaded-plastic backscatter shield which is very effective. With this shield, leaded aprons may not be required by your regulator, but it's always a safe bet to wear the apron anyway.

Pregnancy. Because the fetus is undergoing rapid cell reproduction, it is important to reduce radiation exposure during pregnancy. As the X-ray operator, if you are, or become, pregnant, you should notify your employer immediately. It is your responsibility to declare your pregnancy. For the safety of your patients, you should question the patient regarding the possibility of them being pregnant. If the patient is, or may be, pregnant, they should be advised by your radiation safety officer prior to exposure.

Medical Procedure Doses

Dental imaging procedures contribute to a much lower patient dose than other imaging studies. The table to the right presents typical patient doses associated with various medical imaging procedures.

| Procedure | Dose (mSv) |
|--------------------------------|--------------|
| X-ray (single exposure) | |
| Hand/Foot | 0.005 |
| Dental | 0.015 |
| Chest | 0.10 |
| Abdomen | 0.60 |
| Pelvis | 0.70 |
| Mammogram (2 views) | 0.72 |
| CT(multiple exposures) | |
| Head | 2 |
| Chest | 7 |
| Full Body | 10 |

**Data source: NRC

Worker Radiation Dose Limits

Occupational dose limits are set by regulatory agencies to limit cancer risk as well as the other potential biological effects of radiation. Annual occupational dose limits, as established in U.S. federal law (10 CFR 20) are provided below, however some locally established dose limits may be more protective. Check with your local regulator for dose limits that apply specifically to you.

| Type of Limit | Occupational Dose Limit |
|---------------------------------|--------------------------------------|
| Total effective dose equivalent | 50 mSv |
| Lens of the eye | 150 mSv |
| Skin | 500 mSv |
| Hands and feet | 500 mSv |
| Embryo/fetus | 5 mSv (over the length of pregnancy) |

**from 10CFR20.1202 and 10CFR20.1208

MaxRay Safety

Backscatter Shield

The Cocoon has a circular, lead infused plastic disc (0.35 mm lead-equivalent) surrounding the X-ray beam emission port. The purpose of this “backscatter shield” is to absorb radiation scattered from the patient’s jaw so that it doesn’t reach the operator. The backscatter shield should never be removed, as this shield is very effective at reducing radiation scatter in the direction of the operator. As seen by the figure, the shield, in relation to the patient’s head, provides a safety zone in which the operator should remain during exposures.

(Editor’s Note: The photograph was taken in a studio. In the clinical setting, the patient and technician would be wearing leaded protection.)



The backscatter shield provides a safety zone to the left of the green line.

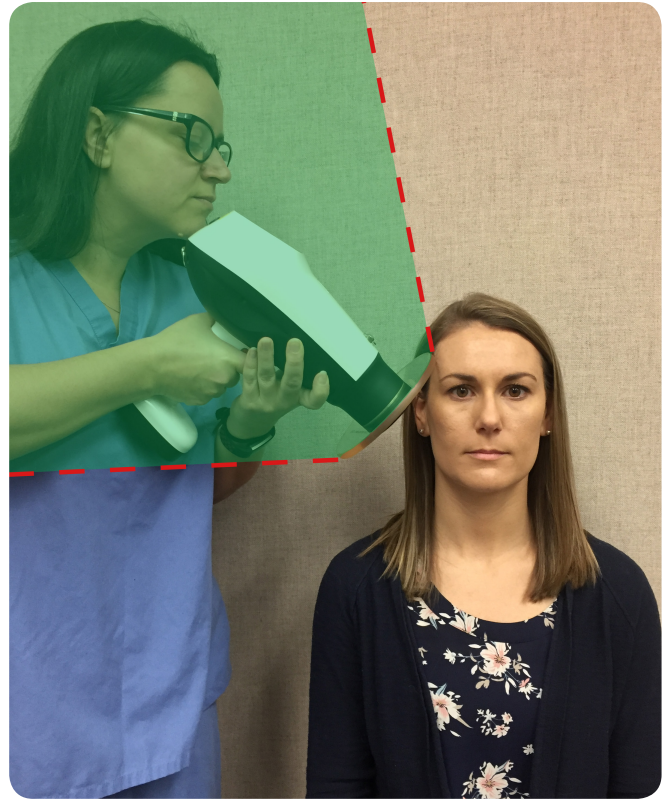
Geometry of the Backscatter Zone

When producing an X-ray image, the operator should stand directly behind the unit, holding it in the manner shown. In order to maximize the backscatter protection area, the emission port should be perpendicular to the area being radiographed, i.e., the backscatter shield should be parallel to the operator.



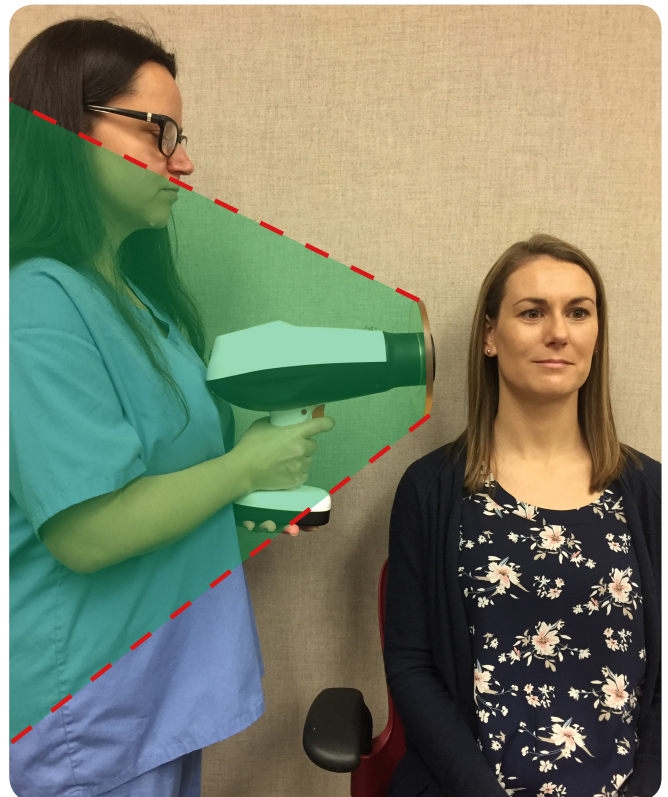
Proper parallel orientation.

If the backscatter shield is not parallel to the operator, the backscatter zone angle changes, limiting the zone coverage. When taking a difficult image, the operator should first attempt to move the patient's head, while maintaining proper alignment. This allows for the operator to stay within the backscatter zone and maintain operator safety. Keeping the backscatter shield parallel to the body is very important. If the operator holds the Cocoon in the manner shown, the shield is not protecting their vital organs and radiation exposure is received unduly.



Improper usage.

Additionally, the emission port should be held close to the patient to maximize the backscatter protection zone. As the cone and shield move farther from the cheek, the angle defining the backscatter protection zone decreases.



Increased distance reduces protection area.

Dosimetry

The Cocoon has been shown to be a very safe handheld X-ray system when used as intended. The occupational dose from leakage radiation at 1 cm from the case is less than 0.05 mSv to the fingers for an entire work year. And, as long as the operator remains within the safety zone (provided by the backscatter shield), their dose to the whole body is less than 0.20 mSv. These dose estimates assume that the operator makes 7,200 dental X-rays each year; the unit is very safe. For reference, the regulatory dose limits are 500 mSv to the fingers and 50 mSv to the whole body.

Accidental Exposure Prevention

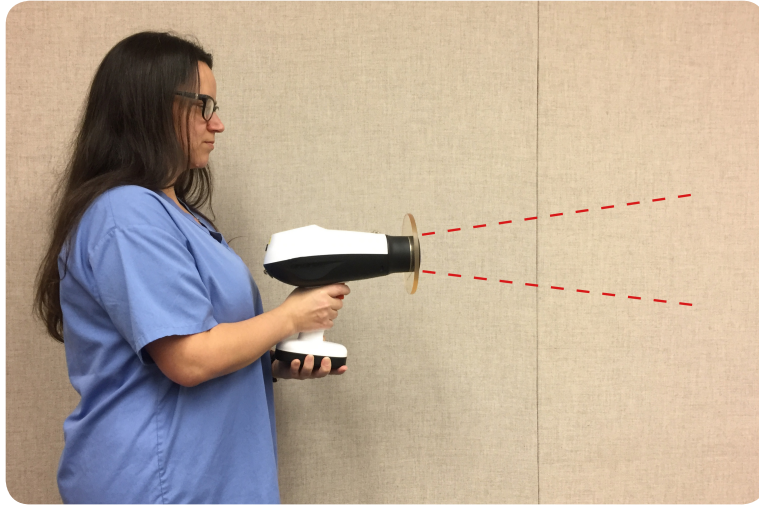
Accidental exposures are easy to prevent if the operator remains aware of the direction in which the emission port is pointing and the on/off status of the Cocoon. As a general rule, whether on or off, the operator should NEVER point the Cocoon emission port at anyone, except the area of the patient about to be radiographed. Exposure occurs only when the activation button is pressed. The operator should remain vigilant and keep their finger off the activation button until ready for the intended exposure.

As the operator, it is important to be aware of your surroundings in order to maintain ALARA. Always ensure that you are within the backscatter protection zone, and that all unnecessary persons are out of the room prior to initiating an exposure.

When taking an image, the current status of the unit on the LCD display window will change from READY to EXPOSURE, accompanied by voice prompting. The operator will hear a steady tone during the exposure; this sound will end when the selected time has passed. As a safety feature, the exposure will stop when the activation button is released, even if the selected time cycle is not complete.



NEVER attempt to operate the Cocoon handheld X-ray system if any covers, shielding material, collimators, etc. have been removed. As the operator, NEVER place any part of your body in the primary beam.







An additional safety feature is provided in the handle of the Cocoon. A trigger lock is available and can be engaged by the operator. With the trigger in the outer position (left picture), the lock is depressed from the left side. This will lock the trigger in the “off” position (right picture), not allowing engagement of the X-ray emission electronics.



Pressing the trigger lock from the right side of the unit will unlock the trigger and allow for normal operation.

Exposure Time

There is only one variable of exposure on the Cocoon unit that can be changed for a given radiograph ... exposure time. The Cocoon has exposure factors of mA and kV that are fixed and cannot be changed by the operator. The exposure time is changed based on patient age (adult or child), image receptor (film or digital), and the location of teeth being imaged. The operator makes selections of age, receptor, and position on the Cocoon, and in turn the Cocoon provides a suggested range of exposure time in increments of 0.05 seconds. For example, a selection of adult, digital (sensor), molar results in suggested time option of 0.40 seconds (see chart below). See the User's Manual for more details on selecting the exposure time.

| Classification | | Teeth types and exposure time | | | | |
|---------------------------------------|--------|-------------------------------|---|--|---|---|
| Tooth | | - |  |  |  |  |
| Distance between cone and skin (18cm) | SENSOR | Adult | 0.10 ~ 0.20 | 0.20 ~ 0.30 | 0.30 ~ 0.40 | 0.40 ~ |
| | | Child | 0.05 ~ 0.15 | 0.15 ~ 0.25 | 0.25 ~ 0.35 | 0.35 ~ |
| | PSP | Adult | 0.20 ~ 0.30 | 0.30 ~ 0.40 | 0.40 ~ 0.50 | 0.50 ~ |
| | | Child | 0.15 ~ 0.25 | 0.25 ~ 0.35 | 0.35 ~ 0.45 | 0.45 ~ |
| | FILM | Adult | 0.30 ~ 0.40 | 0.40 ~ 0.50 | 0.50 ~ 0.60 | 0.60 ~ |
| | | Child | 0.25 ~ 0.35 | 0.35 ~ 0.45 | 0.45 ~ 0.55 | 0.55 ~ |

There is a direct correlation between exposure time and dose. If exposure time is increased, patient dose increases. There is certainly a trade-off between image quality and patient dose. It is important to practice ALARA by keeping dose as low as possible while maintaining adequate image quality for diagnosis. Exposure to the operator and the patient should be limited and having to repeat images should be avoided.



Safe Storage

Because the handheld X-ray system is portable, certain safety precautions must be implemented to ensure worker and patient safety. For a safe work environment, when not in use, the Cocoon should be stored in a locked cabinet so that the device is accessible only to authorized personnel.

